

REMARKS

The first page of the Form PTO-1449 submitted in this case on September 11, 2003, was initialed and signed, with the exception of the last reference on that page. Applicants request a signed copy of that page of the Form PTO-1449 with that reference initialed. A copy of that page is attached as Exhibit 1, for reference.

To the extent that it is not necessary to address particular items within the Office Action in order to provide a complete response, Applicants' choice not to discuss such items is not, and cannot be interpreted as, acquiescence by the Applicants to such items, nor does it or can it be construed during prosecution of this patent application or in any later administrative or judicial action to limit the scope of any claims that may eventually issue in this patent application or any patent application claiming priority to this one.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

For example, where a claim limitation X is present, and four references A, B, C and D are combined to form the set A+B+C+D, the claim limitation X must be present in at least one of the individual references for it to be present in the set of combined references. That is, a limitation that is not present in any one of the references A, B, C, or D cannot be present in

the combination A+B+C+D. This settled law as to 35 U.S.C. §103 and MPEP 706.02(j) is consistent with the cited cases, *In re Merck*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (stating that a reference cannot be “read...in isolation”) and *In re Keller*, 642 F.2d 413, 422-23, 427 (holding that an affidavit concerning only one prior art reference is not sufficient to overcome obviousness rejection as to three separate references).

Claims 1-3, 5-8, 10-18 and 45-57

Claim 1 has been amended to claim “creating at least one point of entry into the thoracic cavity; gaining access to a distal anastomotic site; stabilizing the heart by inserting an integrated stabilizer connected to a tool through at least one point of entry; and performing a distal anastomosis between an end of the graft vessel and the side of the target vessel with said tool while the heart is beating.” (emphasis added).

In contrast, U.S. Pat. Application No. 2003/0010346 to Paolitto (“Paolitto”), U.S. Pat. No. 5,735,290 to Sterman (“Sterman”), U.S. Pat. No. 6,110,187 to Donlon (“Donlon”), and U.S. Pat. No. 6,066,144 to Wolf (“Wolf”), when combined, do not teach or suggest all of the limitations of amended claim 1. None of these references teach or suggest stabilizing the heart by inserting through at least one point of entry an integrated stabilizer connected to a tool; and performing a distal anastomosis between an end of the graft vessel and the side of the target vessel with said tool while the heart is beating. Thus, the combination of these references cannot teach or suggest that claimed subject matter.

Wolf does not teach or suggest a stabilizer, much less a stabilizer connected to a tool used to perform distal anastomosis. While Wolf is a tool that may be used to perform distal anastomosis, nowhere in Wolf is it taught or suggested that Wolf is or even could be connected to an integrated stabilizer. Additionally, Sterman does not teach or suggest a stabilizer, much less a stabilizer connected to a tool used to perform distal anastomosis. The

procedure of Sterman is performed while the patient's heart has stopped, and thus, there is no need to stabilize a portion of a heart that is no longer beating. (*e.g.*, col. 6, lines 8-18). Thus, neither Sterman nor Wolf can contribute a stabilizer to the combination of Paolitto, Sterman, Donlon and Wolf.

Turning to the other two cited references, Paolitto discloses a traditional coronary stabilizer, having two spaced-apart arms that exert force against the heart to stabilize a portion of the heart between those arms. (*e.g.*, paragraphs 0114-0115, 0120-0121; Figures 10-11B). However, Paolitto does not teach or suggest a tool that is connected to the stabilizer and that is used for performing anastomosis, as claimed in claim 1. Rather, the stabilizer is a separate tool unconnected to any tools utilized to perform anastomosis. (*e.g.*, paragraphs 0177, 0183). Donlon discloses "heart engaging members 902" that are connected to a retractor and that extend into a patient's chest cavity through a conventional open-sternum opening and contact the heart. (*e.g.*, col. 70, line 65 through col. 71, line 29; Figures 68-73). However, Donlon does not teach or suggest a tool a tool that is connected to the stabilizer and that is used for performing anastomosis, as claimed in claim 1.

Thus, the combination of Paolitto, Sterman, Donlon and Wolf neither teaches nor suggests the subject matter claimed in claim 1, and Applicants believe claim 1 is in condition for allowance. Claim 1 is generic. Thus, were it to be allowed, claim 1 would be allowed as to all species identified in this application. Further, claims 2, 3, 5-8, 10-18 and 45-57 depend from claim 1, and thus are in condition for allowance under MPEP 608.01(n)(III).

With regard to paragraph 11 of the Office Action, it states that:

The grasper of Sterman splits to release the vessel. A grasper as shown in figure 3, inherently opens the blades (splits) to release the object the blades are holding. (Office Action, page 2, lines 16-17) (emphasis added)

No support for the finding that a grasper inherently provides certain function is provided, as required by MPEP 2112. However, the Office Action later states that:

claim 1 does not requires a grasper or blades currently. Their presence or absence is indeed irrelevant to claim 1. (Office Action, page 5, paragraph 11, lines 14-16) (emphasis added)

Thus, it is admitted on the record that the grasper and blades of Sterman are irrelevant to claim 1. As a result, the grasper and blades of Sterman cannot be prior art to claim 1.

With regard to paragraph 12 of the Office Action, Applicants do not deny that it is “well known in the art to finish anastomosis bypass,” and point out that this phrase appears nowhere in claim 1 prior to or after its amendment herein. In addition, Applicants do not object to the characterization of the construction of claim 1 as set out in paragraph 12 of the Office Action as the “proper” construction.

With regard to paragraph 14 of the Office Action, Wolf does not disclose an end-to-side anastomosis as that term is understood in the art. Attached as Exhibit 2 are pages 223-225 and the copyright page of a medical textbook. (John W. Kirklin, Cardiac Surgery 223-225 (1986)). This text illustrates both end-to-side (page 224, Figure 7-6) and side-to-side (page 225, Figure 7-7) anastomoses. In an end-to-side anastomosis, the end of the graft is connected directly to the side of the target vessel; as a result, no incision is needed in the graft vessel to allow fluid to travel between the vessels. (page 224, Figure 7-6, esp. Figure 7-6b). In a side-to-side anastomosis, the side of the graft is connected to the side of the target vessel; as a result, an incision is needed in each vessel to allow fluid to travel therebetween. (page 225, Figure 7-7). This terminology is standard in the art, and Applicants do not define these types of anastomoses any differently in the specification. Only side-to-side anastomosis is disclosed in Wolf. Figures 13-16 and column 10, lines 24-67 of Wolf clearly show a side-to-side anastomosis, as that term is ordinarily understood in the art. Although Wolf notes in passing that the tool may be used to perform an end-to-side anastomosis, Wolf provides no

drawings and no written disclosure as to how an end-to-side anastomosis could be performed with that tool, and as such Wolf is a non-enabling reference as to end-to-side anastomosis under MPEP 2121.

With regard to paragraph 16 of the Office Action, the term “distal anastomosis tool” is defined in the specification of this patent application. None of these definitions are consistent with or analogous to a “handle.” Thus, Applicants cannot and do not acquiesce in any rejection that analogizes a handle to a distal anastomosis tool.

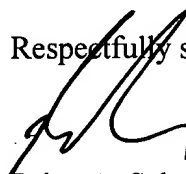
With regard to paragraph 17 of the Office Action, it is standard surgical practice to cut a graft vessel to a length at least as long as expected to be needed, where the surgeon determines that length by visually inspecting the graft. Enough extra length is allowed such that the graft is typically longer than required. After grafting one end of the graft vessel to a first target vessel, the other end of the graft is moved to the second target vessel. If the graft vessel is long enough that kinking may occur, the graft vessel is cut to a shorter length, and the portion of the graft that is cut away is discarded. The free end of the graft is then connected to the second target vessel. Thus, in standard surgical practice, the length of the graft is never measured. Any statement to the contrary is a rejection based on inherency. Under MPEP 2112, support for any finding of inherency must be provided. Applicants request such support to be provided, or in the alternative, that this rejection be withdrawn.

REQUEST FOR ALLOWANCE

Allowance of the pending claims with regard to all species is respectfully requested.

Please contact the undersigned if there are any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'B. A. Schar', written over the word 'submitted'.

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